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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,252	03/21/2001	Nancy D. Hanson	180.0003 0103	6198

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MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MN 55458

EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/814,252	HANSON ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7-11,17-21,24-27,30-38 and 49-57* is/are pending in the application.

4a) Of the above claim(s) *1,2,4,5,7-10,17-21,24-27,30-38 and 49-55* is/are withdrawn from consideration.

5)☒ Claim(s) *11* is/are allowed.

6)☒ Claim(s) *56* is/are rejected.

7)☒ Claim(s) *57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on July 8, 2003 has been entered. The claims pending in this application are claims 1, 2, 4, 5, 7-11, 17-21, 24-27, 30-38, and 49-57 with claims 1, 2, 4, 5, 7-10, 17-21, 24-27, 30-38, and 49-55 withdrawn from consideration as the result of the restriction requirement. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn.

Election/Restriction

2. This application contains claims 1, 2, 4, 5, 7-10, 17-21, 24-27, 30-38, and 49-55 which are drawn to an invention nonelected with traverse in the response filed on December 17, 2002. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments

In page 9, last paragraph bridging to page 10, first paragraph of applicant's remarks, applicant argues that "[A]pplicants also continues to request that Group XIII, drawn to a method for identifying a beta-lactamase in a clinical sample (independent claim 17), and claims including the elected PSEI, PSE4, or CARB3 family beta lactamase and related primers depending therefrom (claims 37 and 38), be examined with Group V. Again, Group XIII, including claims 17, 37, and 38, could be examined with Group V as these claims recite and/or encompass the

primer pair recited in the claims of Group V. Applicants respectfully request reconsideration of the restrictions in this case and submit that the inventions as claimed can be readily evaluated in one search without placing undue burden on the Examiner while a significant burden would be placed on Applicants to prosecute and maintain 13 patents.".

The above arguments have been fully considered and have not been found persuasive toward the withdrawal of the restriction requirement nor persuasive toward the relaxation of same such that Groups V and XIII will be examined together. Although independent claims 37 and 38 of Group XIII includes PSEI, PSE4, or CARB3 families of beta lactamases, the searches for Group V and Group XIII are not coextensive. For example, besides searching PSEI, PSE4, or CARB3 family beta lactamase, Group XIII requires to search other families of beta lactamases such as K1 beta-lactamase recited in claim 34. Therefore, a significant burden will be placed on the examiner and the restriction is proper.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was

commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sandvang *et al.,* in view of Fluit *et al.,* (WO91/08305, published on June 13, 1991).

The claimed inventions are drawn to a diagnostic kit. Claim 56 requires that a diagnostic kit for detecting a PSE1, PSF4, or CARB3 family beta-lactamase comprising: (a) at least one primer pair capable of hybridizing to a beta-lactamase nucleic acid characteristic of the PSE1, PSE4, or CARB3 family of beta-lactamase enzymes; (b) a positive and negative control; and (c) a protocol for identification of the beta-lactamase nucleic acid of interest.

Sandvang *et al.,* teach characterization of integrons and antibiotic resistance genes in Danish multiresistant *Salmonella enterica* Typhimurium DT104. They used two PSE-1 primers, pse-1 F (nucleotides 323 to 342 in forward sequence) and pse-1 B selected from PSE-1 beta-lactamase gene (nucleotides 742 to 723 in backward sequence), to amplify an integron containing PSE-1 beta-lactamase gene (see abstract in page 177 and primer numbers 9 and 10 of Table 2 in page 179).

Regarding claim 56, since two PSE-1 primers, pse-1 F and pse-1 B, are used to amplify a PSE-1 beta-lactamase gene in the method taught by Sandvang *et al.,*(see Table 2 in page 179), pse-1 F and pse-1 B are a primer pair capable of hybridizing to a beta-lactamase nucleic acid

characteristic of the PSE1, PSE4, or CARB3 family of beta-lactamase enzymes as recited in (a) of the claim because these primers hybridize with PSE-1 beta-lactamase gene during the process of amplifying an integron containing PSE-1 beta-lactamase gene. Since strain *Salmonella enterica* Typhimurium DT104 with designation 9412445 is antibiotic sensitive while strain *Salmonella enterica* Typhimurium DT104 with designation 9616368 is antibiotic resistance on Ap, Cm, Sp, Sm, Su, and Te (see table 1 in page 178), strain *Salmonella enterica* Typhimurium DT104 with designation 9412445 and strain *Salmonella enterica* Typhimurium DT104 with designation 9616368 are positive and negative controls respectively for *Salmonella enterica* Typhimurium DT104 with designation 9423245 which is antibiotic resistance on Sp, Sm, and Su as recited in the claim. Since the method taught by Sandvang *et al.,* includes to identify the integron containing pse-1 beta-lactamase gene from bacterial strains, *Salmonella enterica* Typhimurium DT104, using PCR and sequencing (see abstract in page 177), the method taught by Sandvang *et al.,* is a protocol for identification of the beta-lactamase nucleic acid characteristic of the PSE1, PSE4, or CARB3 family of beta-lactamase enzymes as recited in (c) of the claim.

Sandvang *et al.,* do not disclose a bacteria diagnostic kit as recited in claim 56.

Fluit *et al.,* do teach a bacteria diagnostic kit (see pages 24 and 25).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have organized the components and method taught by Sandvang *et al.,* into a kit because the method for identifying a beta-lactamase in a bacteria sample using PCR and sequencing was known at that time the inventions were made and the kit format was utilized not only to assemble a variety of different reagents together but ensure the

quality and compatibility of the reagents. One having ordinary skill in the art at the time the invention was made would have been motivated to assemble reagent (s) of biotechnology methods into a kit in order to obtain the above discussed advantages, thus resulting in instant kit recited in claim 56. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to combine these prior art together because the kit would provide a convenient, efficient, economical way to practice the method of Sandvang *et al.*.

5. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arlet *et al.,* (FEMS Microbiology Letter, 82, 19-26, 1991) in view of Fluit *et al.,* (WO91/08305, published on June 13, 1991).

The claimed inventions are drawn to a diagnostic kit. Claim 56 requires that a diagnostic kit for detecting a PSE1, PSF4, or CARB3 family beta-lactamase comprising: (a) at least one primer pair capable of hybridizing to a beta-lactamase nucleic acid characteristic of the PSE1, PSE4, or CARB3 family of beta-lactamase enzymes; (b) a positive and negative control; and (c) a protocol for identification of the beta-lactamase nucleic acid characteristic of the PSE1, PSE4, or CARB3 family of beta-lactamase enzymes.

Arlet *et al.,* teach construction by polymerase chain reaction and intragenic DNA probes for three main types of transferable beta-lactamases (TEM, SHV, CARB). A CARB probe was amplified in the presence of primers OC-1 (nucleotides 335-354 for forward sequence) and OC-2 (nucleotides 909-922 for back sequence) selected from PSE-4 gene (see Table 2 in page 21 and

left column in page 22, and reference 10 cited by this paper). The CARB probe hybridized with PSE-1, PSE-4, CARB-2, and CARB-3 and CARB-4 (see page 23, right column).

Regarding claim 56, since two SHV primers OC-1 and OC-2 are used to amplify a CARB beta-lactamase gene probe in the method taught by Arlet *et al.*,(see Table 2 in page 21, left column in page 22, and Figure 1 in page 23), OC-1 and OC-2 are a primer pair capable of hybridizing to a beta-lactamase nucleic acid characteristic of the PSE1 (CARB-2, see page 19, right column), PSE4 (CARB-1, see page 19, right column) or CARB3 families of beta-lactamase enzymes as recited in (a) of the claim because these primers hybridize with CARB families of beta-lactamase during the process of amplifying CARB beta-lactamase gene probe. Since the results from colony hybridization assay show that No. 56 of E. Coli strain K12 has a known CARB-3 beta-lactamase gene and No. 58 of E. Coli strain K12 does not have a CARB-3 beta-lactamase gene (see Table 1 in page 21), Nos. 56 and 58 of E. Coli strain K12 are positive and negative controls of CARB beta-lactamase respectively as recited in the claim. Since the method of Arlet *et al.,* includes amplification of beta-lactamase probes by PCR and identification of beta-lactamases in clinical strains by a hybridization assay, and are used to identify CARB beta-lactamases in clinical strains (see Table 1 in pages 20 and 21, right column in page 22, and left column in page 24), the method of Arlet *et al.,* is a protocol for identification of the beta-lactamase nucleic acid of characteristic of the PSE1, PSE4, or CARB3 family of beta-lactamase enzymes as recited in (c) of the claim.

Arlet *et al.*,do not disclose a bacteria diagnostic kit as recited in claim 56.

Fluit *et al.,* do teach a bacteria diagnostic kit (see pages 24 and 25).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have organized the components and method taught by Arlet *et al.,* into a kit because the method for identifying a beta-lactamase in a clinical sample using PCR was known at that time the inventions were made and the kit format was utilized not only to assemble a variety of different reagents together but ensure the quality and compatibility of the reagents. One having ordinary skill in the art at the time the invention was made would have been motivated to assemble reagent (s) of biotechnology methods into a kit in order to obtain the above discussed advantages, thus resulting in instant kit recited in claim 56. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to combine these prior art together because the kit would provide a convenient, efficient, economical way to practice the method of Arlet *et al.*

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Claim 11 is allowed over prior art since SEQ ID NO: 32, SEQ ID NO: 33, and their fill-length complements are new.

8. Claim 57 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims since SEQ ID NO: 32, SEQ ID NO: 33, and their fill-length complements are new.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
September 25, 2003